K110679

510(k) Summary

[in accordance with 21 CFR 807.92(c)]

AUG - 2 2011

Contact: Mr. Hartmut Loch
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Regulatory Affairs & Quality Assurance
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Date Prepared: March 7, 2011

Trade name:
Common name: Spinal Fixation System

Classification name:

Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease	- § 888.3070 (NKB) – class III
Appliance, Fixation, Spinal Interlaminal	- § 888.3050 (KWP) - class II
Spinal Intervertebral Body Fixation Orthosis	§ 888.3060 (KWQ) - class II
Pedicle Screw Spinal System	- § 888.3070 (MNI) - class II
Pedicle Screw Spinal System	- § 888.3070 (MNH) - class II

All Orthopedic Device Panel 87

Product Codes: NKB, KWP, KWQ, MNI, MNH

Device Description and Characteristics: The Del Mar® Pedicle Screw System is intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral space. The Del Mar® Pedicle Screw System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor-made to fit the patient's individual anatomy. Monoaxial screws are supplied in winged and non-winged configurations, in a variety of length, ranging from 30 mm to 100 mm and in 5 mm, 6 mm, 7 mm, 8mm and 9 mm diameter sizes. All sizes are able to receive 5.5mm connecting rods only. Pre-bent rods are available in 10 mm increments from 30 to 120 mm in length.

Additional components, such as a Single Piece Set Screw, Cobalt Chrome Rods ranging from 400 mm to 600 mm and several types of Deformity Connectors have been added. The Del Mar® Pedicle Screw System implant components are fabricated from medical grade titanium alloy per ASTM F136 and Cobalt Chrome alloy per ASTM F1058.

Equivalence: The modified Del Mar® Pedicle Screw System is substantially equivalent to the Del Mar® Pedicle Screw System (K091219 S/E 7/9/2009 and unmodified K051275 S/E 12/9/2005, which is manufactured and marketed by Phygen, LLC.

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Indications: The Del Mar® Pedicle Screw System is intended to be used in skeletally mature patients as an adjunct to fusion using autograft or allograft in posterior, non-cervical fixation for the following conditions:

Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Performance data: The following mechanical tests have been performed per ASTM F1717-10:

a. Static Compression Bending Tests
b. Static Torsion Test
c. Dynamic Compression Bending Tests

In addition the following tests per ASTM F1798-97 (2008) were performed:

d. Static Axial Gripping Capacity
e. Axial Torque Gripping Capacity

The test results were equivalent to the predicate device and/or other similar implants and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Phygen, LLC
% Mr. Hartmut Loch
Vice President
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AUG - 2 2011

Re: K110679
Trade/Device Name: DEL MAR® Monoaxial Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: July 18, 2011
Received: July 19, 2011

Dear Mr. Loch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110679

Device Name(s): DEL MAR® Monoaxial Pedicle Screw System

Indications for Use:

The DEL MAR® Monoaxial Pedicle Screw System is intended to be used in skeletally mature patients as an adjunct to fusion using autograft or allograft in posterior, non-cervical fixation for the following conditions:

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Prescription Use __X__ AND/OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110679